Docket No. 1151-4167

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Chang Yi Wang

Group Art Unit:

1647

Serial No.:

09/865,294

Examiner:

Sharon Turner, Ph.D.

Filed:

May 25, 2001

For:

Immunogenic Peptide Composition for the Prevention and Treatment of Altzheimer's

Disease

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(Signature of person mailing paper(s) and/or fee)

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.

345 Park Avenue

New York, NY 10154-0053

(212) 758-4800 Telephone

(212) 751-6849 Facsimile

Attorney Docket: 1151-4167

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AND TREATMENT OF ALZHEIMERS DISEASE

**Group Art Unit** 

1647

Examiner

Sharon Turner, Ph.D.

Commissioner for Patents Washington, D.C. 20231

Box: Non-fee Amendment

## RESPONSE TO SECOND RESTRICTION REQUIREMENT

Sir:

This is in response to the office action dated February 6, 2003, for which a shortened period of one month was set.

Response begins on this page.

Remarks/Arguments begins on this page.

#### **RESPONSE**

In response to the second restriction requirement, Applicant provisionally elects Claims 1-40 of Group I. As required for a full response to the restriction requirement, Applicant provisionally cancels claims 41-80 subject to reconsideration requested.

The requirement is traversed for the following reasons. Applicant requests that the claims 1-80 of the present application being related and linked should be examined together.

### **REMARKS AND ARGUMENTS**

On October 30, 2002, Applicant responded to an amended restriction requirement electing the species wherein

- T-helper epitope SEQ ID NO: 51, 1.
- 2. fragment of Aβ<sub>1-42</sub> peptide - SEQ ID NO:67, and
- 3. linker -  $(\alpha, \epsilon - N)$ -Lys.

1ECH CENTER 160/2000 The claims that read on the species elected are claims 1-2, 4-10, 12, 24-32, 34-42, 44-62, 64-72, 74-80. SEQ ID NO:73 is the claimed species.

In the present office action, the Examiner has imposed a second restriction requirement restricting the application to the following groups of claims:

- Claims 1-40 drawn to peptide immunogens and compositions ١. comprising the peptide immunogens, classified in class 530, subclass 300.
- Claims 41-60 drawn t a method of preventing or treating 2. Alzheimer's disease, classified in class 514, subclass 2.
- Claims 61-80 drawn to a method of producing antibodies, 3. classified in class 435, subclass 326.

The basis for the restriction requirement as stated by the Examiner is that:

"Inventions II and III are related as processes. The processed are distinct from each other as the processes differ in reagents, steps, functions and effects."

It is clear that the Examiner admits that Group II and Group III claims are related. Claims 41-61 of Group II are methods of use claims directed to methods of treating Alzheimer disease by the use of the compositions of claims 21-40 comprising specific peptide immunogens. Claims 61-80 of Group III are methods by which the compositions of claims 21-40 are employed to generate antibodies to the Aß<sub>1-42</sub> peptide believed to be responsible for Alzheimer's disease.

Thus, contrary to the Examiner's contention, the compositions used to generate the antibodies of Claims 61-80 are identical to the compositions used in Claims 41-60. The steps of generating the antibodies to the Aß<sub>1-42</sub> peptide is the same as that of treating Alzheimer's disease in the patient. Both requires the administration of the compositions of claims 21-40 to the patient. The function and effects are identical in that by administering the compositions of claims 21-40, antibodies to the Aß<sub>1-42</sub> peptide are generated and the antibodies are responsible for ameliorating the Alzheimer disease conditions, i.e., to inhibit the formation of plaques in the brain. They comprise administering the compositions to the patient. It is not clear to the Applicant what is the basis for the Examiner's contention that "the reagents, the steps, functions and effects" are different for inventions II and III.

Moreover, both sets of claims are linked to claims 21-40, directed to the compositions comprising the peptide immunogens of claims 1-20. Thus, the claims of Group II and Group III are not only related but are linked as written. The Examiner failed to show the alleged difference between the claims of Group II and Group III. Under MPEP §809, related and linked claims should be examined together.

The Examiner further stated that:

Inventions I and II-III are related as products and processes of use.

However, the Examiner contends that the process of use can be practiced with alternative peptides. Applicant disagree. The claims must be looked at as written. Claims 41-60 as written recite that the compositions of claims 21-40 of group I are to be used. Claims 41-60 do not read on or cover alternative peptides. Similarly, claims 61-80 recite that the compositions of claims 21-40 of group I are to be used. Claims 61-80 do not recite alternative peptides.

The Examiner further contends that the peptides of group I claims can be used alternatively in a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions. It is not clear how the peptides can used alternatively in a method of treatment, or a method of making antibodies, or a method of screening compounds or a method of detecting compositions.

However, it is clear the claims of Group II and Group III are linked to and depend on the compositions of claims 21-40, which in turn depend on and are linked to claims 1-20. Thus, the claims of Group II and Group III are not only related to the

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claims of Group I, but are also linked thereto. Under MPEP §809, related and linked claims should be examined together.

Applicant hereby requests reconsideration of the restriction requirement so that examination of the application can proceed without further delay.

Respectfully submitted,

Maria C.H. Lin

Registration No. 29,323

Date: <u>March 4, 2003</u>

Morgan & Finnegan, L.L.P. 345 Park Avenue New York, New York 10154 Tel. No. (212) 758-4800 Fax. No. (212) 751-6849